9-9-09

HARNESS DICKEY

2 September 2009

Food and Drug Administration
Division of Dockets Management (HFA-305)
5630 Fishers Lane, Room 1061
Rockville, Maryland 20852

Re: FDA-2008-E-0103

Determination of Regulatory Review Period for Purposes of Patent Extension;
LETAIRIS (74 Fed. Reg. 6635-36)

Dear Sirs:

Gilead Sciences, Inc. ("Gilead"; formerly Myogen, Inc.) is Sponsor of a New Drug Application ("NDA") filed on 18 December 2006 for drug LETAIRIS, which was approved on 15 June 2007. Harness, Dickey and Pierce, P.L.C. ("HDP"), as agent for Gilead is authorized to communicate with the FDA on matters bearing on determination of regulatory review period for LETAIRIS (ambrisentan) under 35 U.S.C. §156(g)(1)(B), as required to file Patent Term Extension Applications.

FDA Finding

FDA determined on 10 February 2009 that the investigational new drug ("IND") application (IND #63,915) effective date for LETAIRIS is 3 May 2002, a date earlier than determined by Gilead.

Gilead Concurrence

Gilead concurs with FDA finding of an earlier effective IND date. On behalf of Gilead, HDP submits comments, along with exhibits herewith, supporting FDA determinations as to LETAIRIS regulatory review period, as published in Federal Register Vol. 74, No. 26, pp. 6635-36 (Exhibit A). References herein to "Gilead" include, as appropriate, activities conducted by predecessor Myogen, Inc. ("Myogen").

Analysis

FDA determined on 10 February 2009 that the investigational new drug ("IND") application (IND #63,915) effective date for LETAIRIS is 3 May 2002 because a previous IND, (IND #63,412) related to ambrisentan, was removed from full clinical hold on that day. A testing phase begins on IND effective date and ends on the date the approval-review phase begins. Typically, an IND becomes effective 30 days after FDA receives the IND (21 C.F.R. §312.40 (b)(1)), but it can become effective before the 30-day period with an earlier notification by FDA that the clinical investigations described in the IND may begin (21 C.F.R. §312.40 (b)(2)). If an IND was placed on clinical hold, the effective date is the date when the FDA informs the sponsor that all clinical hold issues have been resolved (53 Fed. Reg. 7298 (March 7, 1988)).

Where multiple IND's have been filed leading to approval of a drug product, multiple IND effective dates could result from such filings, and the first-filed IND can be a basis for determining a testing phase, see 53 Fed. Reg. 7298 (March 7, 1988):

> "Where multiple IND's are in effect, the agency will consider the testing phase to have begun when the first IND for the approved human drug product became effective."

To get an earlier IND effective date, however, some nexus between the earlier-filed IND and the approval of the drug product is likely necessary, see 53 Fed. Reg. 7298 (7 March 1988):

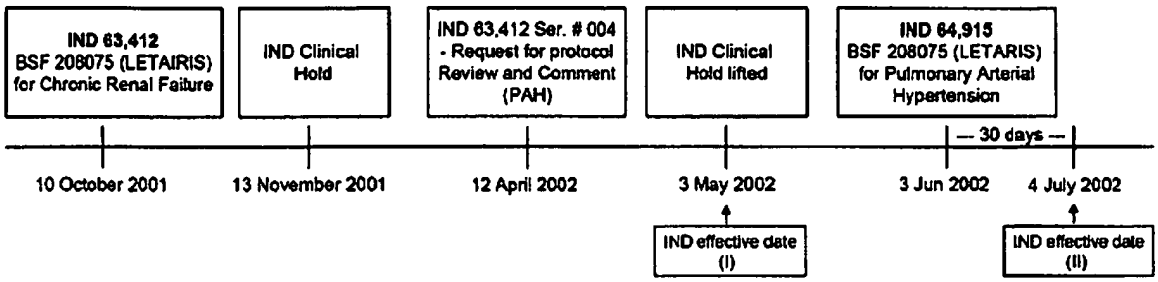
> "While the drug's dosage form and strength during the IND phase need not be identical to that of the approved drug product, the information from the IND studies must have been material to the approval of the drug product."

In sum, a testing phase can be counted from the effective date of an earlier-filed IND if the earlier-filed IND was material to the approval of the drug product.

Based upon search and review of documents and communications between Sponsor Gilead and FDA, HDP and Gilead have reached the same conclusion as FDA that the IND effective date for LETAIRIS is the date when the previous IND (i.e., IND #63,412) was removed from full clinical hold (i.e., 3 May 2002).

Gilead submitted two IND's in connection with clinical study of the active compound, BSF 208075 (ambrisentan). See LETAIRIS IND timeline below and LETAIRIS test phase chronology (Exhibit B).

LETAIRIS IND TIMELINE



A first IND (IND #63,412) was submitted on 10 October 2001 to study BSF 208075 for treatment of chronic renal failure (CRF). The first IND, however, was put on hold on 13 November 2001 because of toxicity issues, but the clinical hold was lifted on 3 May 2002 after submission of a complete response by the Sponsor (Myogen). A second IND (IND #64,915) was filed on 3 June 2002 to study BSF 208075 for treatment of pulmonary arterial hypertension (PAH). Therefore, LETAIRIS has two candidates for IND effective date: (a) the date clinical hold for the first IND was lifted (i.e., 3 May 2002) and (b) 30 days after IND 64,915 submission (i.e., 4 July 2002).

Gilead believes that research activities before IND effective date (a) are material to the approval of the drug product, and accordingly IND effective date (a) should be basis for start of testing phase of LETAIRIS. IND #63,412 (submitted 10 October 2001) was intended to conduct clinical research on BSF 208075 for treatment of CRF. However, the FDA decided to place the IND on hold because of concerns as to potential toxicity of BSF 208075, i.e., testicular atrophy. Gilead had diligently conducted discussions with the FDA relating to a follow-up study for toxicity evaluation and research results until 3 May 2002 when the clinical hold was lifted. The toxicity issue discussed was common to all indications of BSF 208075 including PAH, inasmuch as Dr. Lipicky (FDA Director, Division of cardio-renal

drug products) stated in 9 November 2001 telecon that "the same toxicology problem with the testes exists no matter what the indication." Therefore, research activities and discussions prior to the hold-lifting date (i.e., 3 May 2002) were material for approval of the drug product.

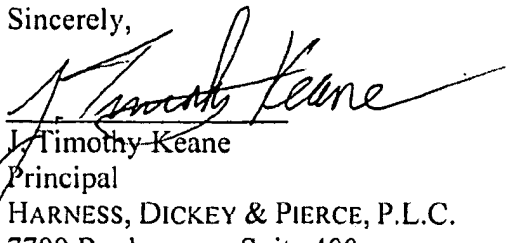
Furthermore, Gilead discussed clinical study strategy and protocol for treatment of PAH during pendency of IND #63,412 for CRF indication. After the FDA clinical hold became effective, Gilead began to discuss possibility of studying other indications including PAH on 14 November 2001 (see summary of 14 November 2001 teleconference, Exhibit B) and then maintained continuous discussions with the FDA on both CRF and PAH research protocols until the clinical hold was lifted. After several rounds of discussion, Gilead submitted "IND #63,412, Serial #004 - Request for Protocol Review and Comment (PAH)" on 12 April 2002, which was designed to investigate PAH indication. Even though IND #63,412 was initially intended to study CRF indication, FDA and Sponsor (Myogen) discussed both CRF and PAH indications substantially under IND #63,412. Thus, such research activities and discussions prior to the hold-lifting date related directly to the approval of LETAIRIS since both IND #63,412 and IND #64,915 were involved in study for treatment of PAH.

Two major topics discussed during IND #63,412 were (1) toxicity issues of BSF 208075 which needed to be resolved to study PAH indication and (2) study protocol for PAH clinical research. Both topics were material and necessary to move forward with IND #64,915 for PAH research. Therefore, IND effective date for LETAIRIS should be 3 May 2001 when the clinical hold for IND #63,412 was lifted.

According to Regulations.gov (a web-based database on Federal regulations and documents), as of deadline of 13 April 2009, no written or electronic comment has been submitted by any other party that any of the dates as published in the Federal Register Notice (Exhibit A) is incorrect as to FDA determination of the regulatory review period of LETAIRIS. See the docket record of FDA-2008-E-0103 (Exhibit C) retrieved from

Regulations.gov on 24 August 2009. Gilead submits the comments above in support of the FDA's determination on LETAIRIS regulatory review period published in the Federal Register Notice.

Sincerely,

By: 

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Attachments

Exhibit A – Federal Register Vol. 74, No. 26, pp. 6635-36

Exhibit B – LETAIRIS test phase chronology

Exhibit C – Docket record of FDA-2008-E-0103, as of 24 August 2009, retrieved from Regulations.gov

C.c.: Mary C. Till, U.S. Patent Office
Madhavi Chander, Gilead Sciences
Paul D. Yasger, Abbott Labs

industry entitled "Updating Labeling for Susceptibility Test Information in Systemic Antibacterial Drug Products and Antimicrobial Susceptibility Testing Devices." FDA is now in the process of finalizing this guidance.

The Food and Drug Administration Amendments Act of 2007 (FDAAA) includes a requirement that FDA identify and periodically update susceptibility test interpretive criteria for antibacterial drug products and make those findings publicly available. The guidance informs industry of how FDA intends to comply with the FDAAA requirement. Specifically, the guidance describes procedures and responsibilities for updating information on susceptibility test interpretive criteria, susceptibility test methods, and quality control parameters in the labeling for systemic antibacterial drug products for human use. The guidance also describes procedures for making corresponding changes to susceptibility test interpretive criteria for antimicrobial susceptibility testing devices.

Description of Respondents: Respondents to this collection of information are holders of new drug applications and abbreviated new drug applications.

Burden Estimate: Application holders can use one of the following approaches to meet their responsibilities to update their product labeling under the guidance and FDA regulations: (1) Submit a labeling supplement that relies upon a standard recognized by FDA in a **Federal Register** notice or (2) submit a labeling supplement that includes data supporting a proposed change to the microbiology information in the labeling. In addition, application holders should include in their annual report an assessment of whether the information in the *Microbiology* subsection of their product labeling is current or changes are needed. For human drugs, this information collection is already approved by OMB under control number 0910–0572 (the requirement in 21 CFR 201.56(a)(2) to update labeling when new information becomes available that causes the labeling to become inaccurate, false, or misleading) and OMB control number 0910–0001 (the requirement in 21 CFR 314.70(b)(2)(v) to submit labeling supplements for certain changes in the product's labeling and the requirement in 21 CFR 314.81(b)(2)(i) to include in the annual report a brief summary of significant new information from the previous year that might affect the labeling of the drug product).

In addition, under the guidance, if the information in the applicant's product labeling differs from the standards recognized by FDA in the **Federal Register** notice, and the applicant believes that changes to the labeling are not needed, the applicant should provide written justification to FDA explainimg why the recognized standard does not apply to its drug product and why changes are not needed to the *Microbiology* subsection of the product's labeling. This justification should be submitted as general correspondence to the product's application, and a statement indicating that no change is currently needed and the supporting justification should be included in the annual report. Based on our knowledge of the need to update information on susceptibility test interpretive criteria, susceptibility test methods, and quality control parameters in the labeling for systemic antibacterial drug products for human use, we estimate that, annually, only two applicants will submit the written justification described on the previous sentences and in the guidance. FDA also estimates that each justification will take approximately 16 hours to prepare and submit to FDA as general correspondence and as part of the annual report.

No comments were received.

FDA estimates the burden of this collection of information as follows:

TABLE 1—ESTIMATED ANNUAL REPORTING BURDEN[1]

Reporting Burden	No. of Respondents	No. of Responses per Respondent	Total Responses	Hours per Response	Total Hours
Justification submitted as general correspondence and in the annual report	2	1	2	16	32

[1]There are no capital costs or operating and maintenance costs associated with this collection of information.

Dated: January 26, 2009.

Jeffrey Shuren,

Associate Commissioner for Policy and Planning.

[FR Doc. E9–2682 Filed 2–9–09; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket Nos. FDA–2008–E–0103, FDA–2008–E–0110, FDA–2008–E–0113, and FDA–2008–E–0114]

Determination of Regulatory Review Period for Purposes of Patent Extension; LETAIRIS

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) has determined the regulatory review period for LETAIRIS and is publishing this notice of that determination as required by law. FDA has made the determination because of the submission of applications to the Director of Patents and Trademarks, Department of Commerce, for the extension of patents which claim that human drug product.

ADDRESSES: Submit written comments and petitions to the Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. Submit electronic comments to *http://www.regulations.gov*.

FOR FURTHER INFORMATION CONTACT: Beverly Friedman, Office of Regulatory Policy, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 51, rm. 6222, Silver Spring, MD 20993–0002, 301–796–3602.

SUPPLEMENTARY INFORMATION: The Drug Price Competition and Patent Term Restoration Act of 1984 (Public Law 98–417) and the Generic Animal Drug and Patent Term Restoration Act (Public Law 100–670) generally provide that a patent may be extended for a period of up to 5 years so long as the patented item (human drug product, animal drug product, medical device, food additive, or color additive) was subject to regulatory review by FDA before the item was marketed. Under these acts, a product's regulatory review period forms the basis for determining the amount of extension an applicant may receive.

A regulatory review period consists of two periods of time: A testing phase and an approval phase. For human drug products, the testing phase begins when the exemption to permit the clinical investigations of the human drug product becomes effective and runs until the approval phase begins. The approval phase starts with the initial submission of an application to market the human drug product and continues until FDA grants permission to market the drug product. Although only a portion of a regulatory review period may count toward the actual amount of extension that the Director of Patents and Trademarks may award (for example, half the testing phase must be subtracted as well as any time that may have occurred before the patent was issued), FDA's determination of the length of a regulatory review period for a human drug product will include all of the testing phase and approval phase as specified in 35 U.S.C. 156(g)(1)(B).

FDA recently approved for marketing the human drug product LETAIRIS (ambrisentan). LETAIRIS is indicated for the treatment of pulmonary arterial hypertension (WHO Group 1) in patients with WHO class II or III symptoms to improve exercise capacity and delay clinical worsening. Subsequent to this approval, the Patent and Trademark Office received four patent term restoration applications for LETAIRIS (U.S. Patent Nos. 5,703,017; 5,840,722; 5,932,730; and 7,109,205) from Abbott Gmbh & Co., KG, and the Patent and Trademark Office requested FDA's assistance in determining these patents' eligibility for patent term restoration. In a letter dated April 22, 2008, FDA advised the Patent and Trademark Office that this human drug product had undergone a regulatory review period and that the approval of LETAIRIS represented the first permitted commercial marketing or use of the product. Shortly thereafter, the Patent and Trademark Office requested that FDA determine the product's regulatory review period.

FDA has determined that the applicable regulatory review period for LETAIRIS is 1,871 days. Of this time, 1,691 days occurred during the testing phase of the regulatory review period, while 180 days occurred during the approval phase. These periods of time were derived from the following dates:

1. *The date an exemption under section 505(i) of the Federal Food, Drug, and Cosmetic Act (the act) (21 U.S.C. 355(i)) became effective*: May 3, 2002. The applicant claims July 4, 2002, as the date the investigational new drug application (IND) became effective. However, FDA records indicate that the IND effective date was May 3, 2002, the date a previous IND was removed from full clinical hold.

2. *The date the application was initially submitted with respect to the human drug product under section 505(b) of the act*: December 18, 2006. FDA has verified the applicant's claim that the new drug application (NDA) for LETAIRIS (NDA 22–081) was initially submitted on December 18, 2006.

3. *The date the application was approved*: June 15, 2007. FDA has verified the applicant's claim that NDA 22–081 was approved on June 15, 2007.

This determination of the regulatory review period establishes the maximum potential length of a patent extension. However, the U.S. Patent and Trademark Office applies several statutory limitations in its calculations of the actual period for patent extension. In its applications for patent extension, this applicant seeks 995 days of patent term extension for U.S. Patent Nos. 5,703,017; 5,840,722; and 5,932,730, and 225 days of patent term extension for U.S. Patent No. 7,109,205.

Anyone with knowledge that any of the dates as published are incorrect may submit to the Division of Dockets Management (see **ADDRESSES**) written or electronic comments and ask for a redetermination by April 13, 2009. Furthermore, any interested person may petition FDA for a determination regarding whether the applicant for extension acted with due diligence during the regulatory review period by August 10, 2009. To meet its burden, the petition must contain sufficient facts to merit an FDA investigation. (See H. Rept. 857, part 1, 98th Cong., 2d sess., pp. 41–42, 1984.) Petitions should be in the format specified in 21 CFR 10.30.

Comments and petitions should be submitted to the Division of Dockets Management. Three copies of any mailed information are to be submitted, except that individuals may submit one copy. Comments are to be identified with the docket number found in brackets in the heading of this document. Comments and petitions may be seen in the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday.

Dated: February 2, 2009.

Jane A. Axelrad,

Associate Director for Policy, Center for Drug Evaluation and Research.

[FR Doc. E9–2683 Filed 2–9–09; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2005–E–0423] (formerly Docket No. 2005E–0255)

Determination of Regulatory Review Period for Purposes of Patent Extension; LUNESTA

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) has determined the regulatory review period for LUNESTA and is publishing this notice of that determination as required by law. FDA has made the determination because of the submission of an application to the Director of Patents and Trademarks, Department of Commerce, for the extension of a patent which claims that human drug product.

ADDRESSES: Submit written comments and petitions to the Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852. Submit electronic comments to *http://www.regulations.gov*.

FOR FURTHER INFORMATION CONTACT: Beverly Friedman, Office of Regulatory Policy, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 51, rm. 6222, Silver Spring, MD 20993–0002, 301–796–3602.

SUPPLEMENTARY INFORMATION: The Drug Price Competition and Patent Term Restoration Act of 1984 (Public Law 98–417) and the Generic Animal Drug and Patent Term Restoration Act (Public Law 100–670) generally provide that a patent may be extended for a period of up to 5 years so long as the patented item (human drug product, animal drug product, medical device, food additive, or color additive) was subject to regulatory review by FDA before the item was marketed. Under these acts, a product's regulatory review period forms the basis for determining the amount of extension an applicant may receive.

A regulatory review period consists of two periods of time: A testing phase and an approval phase. For human drug products, the testing phase begins when the exemption to permit the clinical investigations of the human drug product becomes effective and runs until the approval phase begins. The approval phase starts with the initial submission of an application to market the human drug product and continues until FDA grants permission to market

Ambrisentan (BSF 208075) Test Phase Chronology (IND 63,412 and IND 64,915)

	Date	Document Type	Document Title	Discussed Matter
1	10/10/2001	FDA submission – IND	Initial submission – IND on BSF 208075 for Chronic Renal Failure	
2	11/02/2001	FDA correspondence – Phone call	FDA Contact Report – Clinical Hold	N/A
3	11/09/2001	FDA correspondence – Phone call	FDA Contact Report – To discuss IND and the reasons it is being placed on Clinical Hold	"a) the potential of BSF 208075 to cause testicular tubular atrophy in humans…" "b) the potential of BSF 208075 to cause liver toxicity in humans…"
4	11/13/2001	FDA correspondence – Letter	IND Clinical Hold letter for BSF 208075	"The Agency is particularly concerned about the state of knowledge regarding testicular effects."
5	11/14/2001	FDA correspondence – Phone call	FDA Contact Report – To ask about a potential IND for BSF 208075 for an indication of Pulmonary Arterial Hypertension	"I called and asked Zelda about an IND for BSF 208075 for Pulmonary Arterial Hypertension. I asked if an entirely new IND would need to be submitted…" "She said it may be possible to use the same IND… she said she had checked with her supervisor and the supervisor said to submit another IND for Pulmonary Hypertension."
6	11/19/2001	FDA correspondence – Phone call	FDA Contact Report – To ask about the letter received from the Division and see when to expect the Clinical Hold letter	"I then asked when to expect the IND Clinical Hold letter for BSF 208075. She said the letter was supposed to go out on November 9th, but they had computer problems so it was not signed until November 13th."
7	12/07/2001	FDA correspondence – Phone call	FDA Contact Report – To ask when the FDA minutes from the November 9th teleconference would be available and to ask about the	"I called and asked Zelda when the minutes from the November 9th teleconference regarding the clinical hold on BSF 208075 would be available." "I called Zelda back and asked about the mention in the clinical hold letter of hypertension rather than

	Date	Document Type	Document Title	Discussed Matter
			mention of "hypertension" as the target indication in the clinical hold letter	renal failure as the target indication."
8	12/12/2001	FDA correspondence – Fax	Minutes of 11/9/01 Telecon from FDA	"Dr. Lipicky said the same toxicology problem with the testes exits no matter what the indication."
9	12/14/2001	FDA correspondence – Phone call	FDA Contact Report – To revise the clinical hold letter and to confirm that Dr. Lipicky had referred to the Advisory Committee meeting scheduled for 1/17/01.	"Zelda also said that they would revise the clinical hold letter for BSF 208075 to take out the inadvertent use of the word hypertension as the target indication."
10	12/18/2001	FDA correspondence – Letter	Revised IND Clinical Hold letter for BSF 208075 (the November 13, 2001 letter is superseded by this version.)	
11	12/20/2001	FDA correspondence – Fax	Type A meeting request	"BSF 208075 is currently in development for potential treatment of chronic renal failure (CRF) and primary arterial hypertension (PAH)" "Objectives/outcomes expected from the meeting: … To discuss a clinical development plan for the treatment of patients with PAH, that includes women only in the initial dose-ranging study and uses 6-minute walk as the primary efficacy endpoint."
12	1/16/2002	FDA correspondence	FDA Contact Report – To discuss the Agency's preclinical concerns, a different dose-ranging study for CRF, the overall clinical development strategy including an indication of PAH and confirm that the plan for a Clinical Hold Complete	"GENERAL COMMENTS… The Agency said BSF 208075 is not the average drug candidate and they would put special requirements on it for approval. They said the drug must prove itself to be unequivocally valuable and should ideally distinguish itself from bosentan, i.e., prove to be more safe, more efficacious, or expand the PAH patient population in which efficacy and safety are demonstrated."

	Date	Document Type	Document Title	Discussed Matter
			Response is acceptable.	"6. Would the BSF 208075 clinical development program for treatment of patients with PAH, consisting of the proposed Phase II study in women (see Attachment 3) and a single Phase III study in men and women, fulfill regulatory requirements for an NDA submission? RESPONSE: The Agency said that generally they would require similar data to what was submitted for bosentan, i.e., that generated from two trials using the 6-minute walk test."
13	1/25/2002	FDA correspondence – Phone call	FDA Contact Report – To discuss the toxicology follow-up study and determination of the therapeutic index in rats	"Myogen is most interested in this relative to the two indications they are considering: Chronic Renal Failure (CRF) and Pulmonary Arterial Hypertension (PAH). For PAH, Myogen is considering a microcrotaline model, using several different doses, with dosing to steady state."
14	4/12/2002	FDA submission – IND	IND 63,412, Serial #004 – Request for Protocol Review and Comment (PAH)	"This submission is in response to a recommendation received from the Agency at a meeting with Myogen for IND 63,412 that was held on January 16, 2002. During that meeting a proposal to also investigate the use of BSF 208075 in patients with Pulmonary Arterial Hypertension (PAH) was discussed." "Myogen understands that a separate BSF 208075 IND for the indication of PAH will be required and plans to submit the separate IND as soon as possible, upon receipt of your comments regarding the acceptability of the proposed protocol."
15	4/12/2002	FDA correspondence – Phone call	FDA Contact Report – To confirm that the Clinical Hold complete Response had been received at FDA	"I stated that I was submitting it to the existing IND for Chronic Renal Failure, but understood that a different IND would eventually be needed."
16	5/02/2002	FDA correspondence – Phone call	FDA Contact Report – To confirm that Amendment	"I called Zelda and left a message asking her to let me know if she received the submission with the

	Date	Document Type	Document Title	Discussed Matter
			to the Complete Response to Clinical Hold had been received at FDA and to ask about having a meeting with the Division on May 9, 2002 to discuss the Protocol for PAH.	Amendment to the Complete Response to Clinical Hold. I also asked her if she thought the Division would be willing to meet with use after the Clinical Hold Review Committee Meeting on May 9th to discuss the Protocol Review Request for Pulmonary Arterial Hypertension (PAH)."
17	5/03/2002	FDA correspondence – Phone call	FDA Contact Report – To inform me that the Clinical Hold for IND 63,412 was officially lifted and to offer a teleconference to discuss the protocol for Pulmonary Arterial Hypertension.	"I said that the documents (PAH Protocol, Informed Consent and Investigator's Brochure) were previously submitted but that we would make the same changes to the PAH protocol and informed consent form that had been made earlier this week to the Renal Failure documents and submit them again."
18	5/03/2002	FDA correspondence – Letter	FDA letter lifting clinical hold	"We have completed the review of your submission, and have concluded that clinical trial (AMB-201) may be initiated."
19	6/03/2002	FDA correspondence – Phone call	FDA Contact Report – To inform Zelda that the BSF 208075 IND for Pulmonary Arterial Hypertension was shipped to FDA on June 3, 2002.	
20	6/03/2002	FDA correspondence – Phone call	FDA Contact Report – To check on and confirm the receipt on the IND submission	"I further explained that based on her recommendation in a previous phone contact, all of the preclinical study reports were reprinted in this IND, and not cross-referenced to the reports in the BSF 208075 IND for Chronic Renal Failure (IND 63,412) in order to increase the ease of review."

60580006.1

Exhibit C

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Patent Term Extension Application for LETAIRIS (ambrisentan), U.S. Patent No. 5,932,730

Docket ID: FDA-2008-E-0103 **Agency:** FDA

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Title	Patent Term Extension Application for LETAIRIS (ambrisentan), U.S. Patent No. 5,932,730
Type	Nonrulemaking
Center	CDER
Docket Item Code	E

Items in the Docket Folder

Title	Document Type	Submitter Name	Organization	Document ID	View As...
USTPO to FDA/CDER - Letter	OTHER			FDA-2008-E-0103-0001	PDF HTML
Abbott GmbH & Co. KG - Patent Term Extension Application	OTHER			FDA-2008-E-0103-0002	PDF
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USPTO to FDA/CDER - Letter	OTHER			FDA-2008-E-0103-0004	PDF HTML
FDA/CDER to the USPTO - Letter	OTHER			FDA-2008-E-0103-0005	PDF HTML
Determination of Regulatory Review Period for Purposes of Patent Extension; LETAIRIS	NOTICES			FDA-2008-E-0103-0006	PDF HTML

Page 1 of 1 Displaying 1 - 6 of 6